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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/551,151 | 05/18/2006 | George C. Prendergast | 3882-P03161-US | 4302 |

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| EXAMINER |
|---|
| STONE, CHRISTOPHER R |

| ART UNIT | PAPER NUMBER |
|---|---|
| 4173 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/551,151 | PRENDERGAST ET AL. | |
| | Examiner | Art Unit | |
| | Christopher R. Stone | 4173 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, drawn to a method of treating cancer comprising administering an STI and an IDO inhibitor.

Group II, claim(s) 12-17, drawn to a pharmaceutical composition comprising an STI and an IDO inhibitor.

Group III, claims 18-21, drawn to a method of treating cancer comprising administering an STI or a chemotherapeutic agent, and an immunomodulator, other than IDO inhibitor.

Group IV, claims 22-30, drawn to a method of treating a chronic viral infection comprising administering and IDO inhibitor and a chemotherapeutic agent.

Group V, claims 31-34 and 48-52, drawn to a pharmaceutical composition comprising and IDO inhibitor and a chemotherapeutic agent.

Group VI, claims 35 and 36 drawn to a method of treating cancer comprising administering an IDO inhibitor.

Group VII, claim 37, drawn to a pharmaceutical composition comprising and IDO inhibitor.

Group VIII, claims 38-47, drawn to a method of treating cancer comprising administering an IDO inhibitor and a chemotherapeutic agent.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: IDO inhibitors are not novel (see U.S. Patent No. 6451840, column 4, paragraph 2). Therefore a holding of lack of unity of invention against Inventions I-VIII is proper.

***Rejoinder Notice***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Species Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically if Applicant elects Group I, Applicant is required to elect a single disclosed combination of STI(s) and IDO inhibitor(s) by electing an STI or STIs from the list in claim 3 and an IDO inhibitor or IDO inhibitor(s) from the list in claim 5. Applicant is further required to elect a single disclosed species of cancer from the list in claim 11. If Applicant elects Group II, Applicant is required to elect a single disclosed combination of STI(s) and IDO inhibitor(s) by electing an STI or STIs from the list in claim 14 and an IDO inhibitor or IDO inhibitor(s) from the list in claim 16. If Applicant elects Group III, Applicant is required to elect a single composition of immunomodulator and STI or immunomodulator and chemotherapeutic agent by electing a species of immunomodulator from claim 19, and an STI from claim 21 or a chemotherapeutic

agent from claim 20. If Applicant elects Group IV, Applicant is required to elect a single species of IDO inhibitor from claim 23 and a single disclosed species of chemotherapeutic agent from the list in claim 25. Applicant is further required to elect a single disclosed species of viral infection from the list in claim 30. If Applicant elects Group V, Applicant is required to elect a single species of IDO inhibitor from claim 31 and a single disclosed species of chemotherapeutic agent from the list in claim 34. If Applicant elects Group VI, Applicant is required to elect a single disclosed species of IDO inhibitor from the list in claim 35 and a single species of cancer from the list in claim 36. If Applicant elects Group VII, Applicant is required to elect a single disclosed species of IDO inhibitor from the list in claim 37. If Applicant elects Group VIII, Applicant is required to elect a single disclosed species of IDO inhibitor from claim 41 and a single species of chemotherapeutic agent from the list in claim 39. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Currently all claims are generic. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: The species are compounds with differing chemical structures and properties and diseases with differing mechanisms and clinical effects.

***Inventorship Notice***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Stone whose telephone number is (571) 270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

05November2007
CRS

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